Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JEFFREY A. ROBL, REX A. PARKER,
SCOTT A. BILLER, HARIS JAMIL,
BRUCE L. JACOBSON, and KRISHNA KODUKULA

Appeal No. 2004-0597
Application No. 09/391,053

ON BRIEF

Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, 5-11, 14, and 15, all of the claims remaining. Claim 1 is representative and reads as follows:

1. A method for treating diabetes, insulin resistance, obesity, hyperglycemia, hyperinsulinemia, or elevated fatty acids, or glycerol, or hypertriglyceridemia which comprises administering to a mammalian species in need of treatment a therapeutically effective amount of an aP2 inhibitor.

The examiner relies on the following reference:

Hotamisligil et al. (Hotamisligil), "Uncoupling of Obesity from Insulin Resistance Through a Targeted Mutation in aP2, the Adipocyte Fatty Acid Binding Protein," Science, Vol. 274, pp. 1377-1379 (1996)

Claims 1, 2, 5-11, 14, and 15 stand rejected under 35 U.S.C. § 103 as obvious in view of Hotamisligil and Appellants' alleged admission in the specification.

We reverse.

Background

"aP2, an abundant 14.6 [k]Da cytosolic protein in adipocytes, and one of a family of homologous intracellular fatty acid binding proteins (FABPs), is involved in the regulation of fatty acid trafficking in adipocytes and mediates fatty acid fluxes in adipose tissue." Specification, page 1. The specification states that Hotamisligil "report[ed] that aP2-deficient mice placed on a high fat diet for several weeks developed dietary obesity, but, unlike control-mice on a similar diet, did not develop insulin resistance or diabetes." Id.

The specification discloses a method "for treating diabetes, especially Type II diabetes, and related diseases such as insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids or glycerol, obesity and hypertriglyceridemia," comprising administering an effective amount of an aP2-inhibiting drug to the patient suffering from the disease. The specification also discloses that "[e]xamples of aP2 inhibitors suitable for use herein include compounds which include an oxazole or analogous ring. Thus, U.S. Patent

5,218,124 to Failli et al[.] . . . discloses compounds, which have activity as aP2 inhibitors and thus [are] suitable for use herein." Page 4.

Discussion

Claim 1, the only independent claim on appeal, is directed to a method of treating "diabetes, insulin resistance, obesity, hyperglycemia, hyperinsulinemia, or elevated fatty acids, glycerol, or atherosclerosis," comprising administering to the patient a therapeutically effective amount of an aP2 inhibitor.

The examiner rejected the claims as obvious "over Hotamisligil et al. in view of Failli et al. (USPN 5,218,124) as disclosed in the specification beginning at the top of page 4." Examiner's Answer, page 3 (emphasis omitted). The examiner noted that Hotamisligil teaches that mice deficient in aP2 do not develop diabetes, but "does not teach that the elected oxazole compound specie is an aP2 inhibitor." Id., pages 3-4. The examiner characterized Failli as "teach[ing] that oxazole derivative compounds including the elected compound herein are known aP2 inhibitors." Id., page 4. The examiner did not point to any specific disclosure in Failli as supporting this characterization, apparently relying on the specification's "admission" on page 4.

Appellants argue that the examiner has misconstrued the discussion of Failli in the specification. See the Appeal Brief, page 3: "Appellants have discovered that numerous known compounds are capable of inhibiting aP2. . . . While these compounds—themselves—were known in the art . . ., their ability to inhibit aP2 was not appreciated and thus their potential to treat diabetes is not suggested." See also id., page 5: "The language latched-onto by the

Ex[am]iner, merely observes the fact that Appellants have discovered that Failli's known compounds have an additional—unrecognized—utility."

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A proper § 103 analysis requires "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

In this case, we agree with Appellants that the combined teachings of Hotamisligil and Failli would not have suggested the method of claim 1. As admitted in the specification, Hotamisligil disclosed that mice with homozygous mutations in the aP2 gene did not develop insulin resistance or diabetes, even under conditions that led to insulin resistance in wild-type mice. Thus, Hotamisligil can reasonably be said to suggest inhibition of the aP2 gene product as a method of preventing insulin resistance or diabetes. However, Hotamisligil does not disclose any compounds as aP2 inhibitors.

For this disclosure, the examiner relies upon Failli. However, the examiner has pointed to no particular part of Failli as teaching that the compounds disclosed therein have the property of inhibiting aP2, or are otherwise useful in treating or preventing diabetes or related conditions. (Nor

have we found such a disclosure in our review of the reference.) Instead, the examiner cites the specification's "admission" regarding the teachings of the reference and argues that the reference's actual disclosure is irrelevant, since Appellants have "admitted" that it teaches compounds as aP2 inhibitors.

We disagree with the examiner's position. The relevant passage from the specification states that "[e]xamples of aP2 inhibitors suitable for use herein include compounds which include an oxazole or analogous ring. Thus, U.S. Patent 5,218,124 to Failli et al[.] . . . discloses compounds, which have activity as aP2 inhibitors and thus [are] suitable for use herein." Page 4. The statement with regard to Failli's disclosure is at best ambiguous with respect to what is actually disclosed in the reference. It could be read to say that Failli discloses compounds and discloses their activity as aP2 inhibitors. Equally plausibly, however, it could be read to say that Failli discloses only the compounds (which, incidentally, have activity as aP2 inhibitors).

In view of this ambiguity, we cannot say that the specification provides sufficient evidence of what was known in the art to support a rejection under § 103, which must be shown by a preponderance of the evidence. Cf. In re Nomiya, 509 F.2d 566, 571, 184 USPQ 607, 611-12 (CCPA 1975) ("By filing an application containing Figs. 1 and 2, labeled prior art, ipsissimis verbis, and statements explanatory thereof, appellants have conceded what is to be considered as prior art in determining obviousness of their improvement.").

In addition, the Nomiya court stated that "[i]t is necessary to consider everything appellants have said about what is prior art to determine the exact

scope of their admission." Id. at 571, 184 USPQ at 612. In this case, Appellants have argued that the specification admits only that Failli disclosed certain compounds, not their activity as aP2 inhibitors. See the Appeal Brief, pages 3-5. When we consider everything Appellants have said, we must conclude that the examiner has misconstrued the scope of their admission.

The rejection, therefore, stands or falls on the actual disclosure of the reference. The examiner has pointed to nothing actually disclosed in Failli that would have suggested the method of the instant claims, alone or in combination with Hotamisligil. Thus, the examiner has not made out a prima facie case of obviousness.

Summary

The examiner has not shown that the prior art would have suggested the method of the instant claims. The rejection under 35 U.S.C. § 103 is reversed.

REVERSED

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Administrative Patent Judge)
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